



PATENT

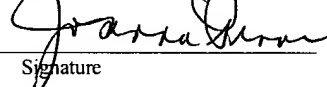
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number. : 09/237,605
Applicants : Richard J. Lazzara et al.
Filed : January 25, 1999
Title : Infection-Blocking Dental Implant
TC/A.U. : 3738
Examiner : Paul Prebilio
Docket Number : 47168-00035USC1
Customer Number : 30223

CERTIFICATE OF MAILING

37 C.F.R. 1.8

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REPLY BRIEF UNDER 37 C.F.R. 41.41

Sir:

A Notice of Appeal was received at the USPTO on December 27, 2004 in the subject application. An Appeal Brief was filed April 27, 2005. An amended Appeal Brief was submitted on August 12, 2005 pursuant to a notification of Non-Compliant Appeal Brief under 37 C.F.R. 41.37(d) mailed July 11, 2005 ("Appeal Brief"). The Examiner's Answer was mailed on April 5, 2006, and this Reply Brief is being submitted pursuant to 37 C.F.R. 41.41.

STATUS OF CLAIMS

The claims have the following status:

<u>Claim No.</u>	<u>Status</u>
1-10	Cancelled
11-16	Cancelled
17-50	Cancelled
51	Rejected and appealed
52-56	Cancelled
57-59	Cancelled
60-75	Rejected and appealed

No claims have been allowed.

Claims 51 and 60-75 were rejected under 35 U.S.C. § 103(a) as being obvious in view of the combination of JP 3-146679 to Haruyuki et al (“Haruyuki”) and U.S. Patent No. 5,571,017 to Niznick (“Niznick”).

Claims 51 and 60-75 are being appealed.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Only one rejection remains for review. Claims 51 and 60-75 were rejected under 35 U.S.C. § 103(a) as being obvious in view of the combination of Haruyuki and Niznick. Haruyuki was cited for disclosing an acid-etched titanium implant, including dental implants, with recesses having average depths of 0.5 to 5 microns. Niznick was cited for teaching that it was known in the art to have different regions of roughness below the top surface, a tapered section, and a self-tapping feature.

ARGUMENT

In the Examiner's Answer ("Answer"), mailed on April 5, 2006, the Examiner has revisited many of the same arguments regarding the claimed invention and the Haruyuki et al. ("Haruyuki") English Translation of Japanese Patent No. 3-146679 and U.S. Pat. No. 5,571,017 to Niznick ("Niznick").

The Examiner's rejection relies on Haruyuki for disclosing an acid-etched titanium dental implant. Recognizing that Haruyuki does not disclose distinct sections for locating this acid-etched surface, the Examiner's rejection relies on Niznick for teaching that it was known in the art to have different roughness at different locations on the dental implant.

The Appeal Brief presents nine points of contention in support of the patentability of the various claims. Those nine contentions are:

1. Haruyuki's treatment is not a "similar type of process" as the claimed invention, and does not "inherently" produce same surface. Appeal Brief, pp 7-9.
2. Haruyuki's second step "smoothens" the underlying surface – it does not roughen it. Appeal Brief, p. 7.
3. Niznick and Haruyuki do not teach all of the elements of claim 51. Appeal Brief, p. 9.
4. Niznick and Haruyuki teach away from their combination. Appeal Brief, p. 10-11.
5. Niznick teaches away from the claimed invention. Appeal Brief, p. 12.
6. Niznick and Haruyuki do not teach all of the elements of claim 63. Appeal Brief, p. 13.
7. Niznick and Haruyuki do not teach all of the elements of claim 68. Appeal Brief, p. 14.
8. Niznick and Haruyuki do not teach all of the specific elements of dependent claims 61, 67, and 72. Appeal Brief, p. 15.
9. Dr. Porter's Declaration establishes secondary evidence of non-obviousness. Appeal Brief, pp 15-17.

The Answer **must** address each of the contentions set forth in the Appeal Brief. This is spelled out in detail in Section 1207.02 of the MPEP.

“(10) *Response to Argument*. A statement of whether the examiner disagrees with each of the contentions of appellant in the brief with respect to the issues presented and an explanation of the reasons for disagreement with any such contention. **>The examiner must use headings and subheadings paralleling the headings and subheadings utilized in the appellant's brief.”

In addition to the fact that the Answer does not “track” the headings and subheadings of Arguments in the Appeal Brief, the Answer fails to address several of the points of contention in the Appeal Brief. The Applicants will now briefly address the infirmities in the Answer as they relate to each of the nine contentions.

1. Haruyuki Teaches a Different Process The Produces A Different Surface

The Examiner contends that “since a similar type of etching process is used ...”, Haruyuki’s surface would “inherently” be the same as the Applicants’ surface. Answer, page 4. The Examiner further posits that “the Examiner does not see any clear difference between the two, to the extent that one looking at one or the other would not know if Haruyuki’s or Appellants’ treatment method was used.”

However, Exhibit H of the Appeal Brief and the micrographs from Exhibit I, particularly Exhibits A and B of Exhibit I **do**, in fact, show clear differences between the produced by the Haruyuki’s surfaces and Appellants’ surfaces. Both the SEM and 3-D Surface Map of the Appellants’ Osseotite® surface, shown in Exhibit A of Dr. Gubbi’s Declaration, have much rougher appearing peaks and more widely distributed peaks compared to Haruyuki’s method. Looking specifically at the SEM and 3-D Surface Map for Example 2 in Exhibit B of Dr. Gubbi’s Declaration, the elements present on the sample made using Haruyuki’s method are spotted along machining lines on the surface and, thus, do not show a “uniform array of irregularities.” Even Dr. Gubbi states that the “machining marks are still visible on many of the surfaces” of the samples produced in accordance to Haruyuki. Dr. Gubbi Decl. ¶¶H. Thus, there are visible differences are present between the Appellants’ surface and Haruyuki’s surface.

Again, it is noteworthy that Dr. Gubbi could **not** replicate the Haruyuki's surfaces set forth in the Haruyuki micrographs.

2. Haruyuki "Explicitly" Teaches the Second Treatment Smoothens the Surface

The Examiner further states that "Haruyuki does not teach smoothing the surface" and that "smoothness is not explicitly discussed." Answer, page 6. There is no question that Haruyuki's second treatment step is for smoothing the surface produced by the first treatment. Haruyuki states that "[d]ipping in a mixed aqueous solution of HF and H₂O₂ in the posttreatment functions to **smooth** the sharp edges and sharp spines that appear at the microscopic depressions produced during the pretreatment." Haruyuki, page 4, col. 2, emphasis added. Haruyuki provides substantial reasoning for the smoothing nature of second treatment that "the appearance of sharp spines and sharp edges at the ridge lines between depressions, which can cause tissue irritation (**possibly a trigger for cancer**)."
Id., page 4, col. 1.

Thus, Haruyuki clearly teaches that the second treatment is used to smoothen the surface, as smoothing sharp edges and sharp spines would smooth the surface. The Examiner statement that "smoothness is not **explicitly** discussed" (Answer, page 6; emphasis added) is totally in error. Haruyuki **explicitly** teaches that the second treatment is to smoothen the roughened surface produced by the first treatment and **explicitly** teaches the reasoning behind this smoothing.

3. Haruyuki and Niznick Fail to Disclose All Elements of Claim 51

Claim 51 requires, below the smooth head portion, a uniformly acid-etched surface extending from the threaded portion all the way to the lowermost end. The uniformly acid-etched surface has a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns. Appeal Brief, p. 9. The Answer does **not** explicitly state where Niznick or Haruyuki teaches a uniformly acid-etched surface having a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns that extends from the threaded portion all the way to the lowermost end. The Answer cannot make this statement because Niznick and Haruyuki fail to teach this feature on a dental implant.

Haruyuki mentions his surface could be used on dental implants. But, Haruyuki does not state where to locate any roughened surface on the dental implant, or even what type of dental

implant he is referring to. Haruyuki provides absolutely no teaching regarding why a roughened surface should be at only certain locations on the dental implant, as opposed to a smooth surface on other locations.

Niznick teaches the main portion of the implant's surface should be average peak-to-valley distance of the surface texture being 25 microns or greater, **and** that the surface texture with the peak-to-valley heights of 25 microns or greater should be created from an HA (hydroxylapatite) coating, TPS (titanium plasma spray) coating, or grit blasting, all of which introduce foreign matter to the underlying implant surface (**i.e., not acid-etching**). Niznick, Col. 7, lines 17-18 and 47-48. Furthermore, Niznick teaches the lowermost portion of the dental implant should have a **different** surface topography from the main portion of the implant. Hence, neither reference alone, or in combination, discloses a uniform acid-etched surface extending from the threaded portion to the lowermost end.

4. Niznick and Haruyuki Teach Away From Their Combination

The Answer states that both Niznick and Haruyuki may be combined as they both deal with "rough surfaces for the purpose of ongrowth and ingrowth that the different dimensions alone do not make them incompatible." Answer, page 6. The Answer further indicates that disclosed or preferred embodiments do not constitute teaching away. *Id.* However, the law of obviousness requires that a reference be considered as a whole, including those portions that teach away from the Applicant's claimed invention. See *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.3d 1540, 1550-51, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983) ("[T]he totality of a reference's teaching must be considered."); see also M.P.E.P. § 2141.02 (stating that prior art must be considered in its entirety including disclosures that teach away from the claims). Indicia of teaching away in a reference gives insight into the question of obviousness. *Monarch Knitting Mach. Corp. v. Sulzer Morat GMBH*, 139 F.3d 877, 885, 45 U.S.P.Q.2d 1977, 1984 (Fed. Cir. 1998). A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Monarch Knitting*, 139 F.3d at 885, 45 U.S.P.Q.2d at 1994 (quoting *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q. 1130, 1131 (Fed. Cir. 1994)). In fact, the United States Court of Appeals for the Federal Circuit has stated that "references that teach away cannot serve to create a *prima*

facie case of obviousness.” *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001).

Haruyuki discloses a desire for a very specific type of surface with an average depth of between 0.5 microns and 5 microns, and that a greater depth may even cause cancer. Appeal Brief, p. 10. Thus, Haruyuki is very concerned that if the depth of the microscopic depressions on the implant’s surface exceeds 5 microns, there is a detrimental effect.

Niznick teaches that the implant’s surface should be five times rougher than Haruyuki with an average depth on the middle section of the implant being at least 25 microns, and the depth on the rest of the implant being at least 20 microns. Appeal Brief, p. 10-11.

The Answer seems to suggest that the Applicants’ position for patentability focuses only on a limited portion of Niznick. This is not true. All of Niznick’s disclosure entails a surface texture with 25 micron or greater peak-to-valley heights in the middle section of an implant and at least 20 micron or greater peak-to-valley height within the rest of the implant. Thus, a skilled artisan would learn from Niznick that a peak-to-valley heights should be at least 20 microns on a “relatively smooth” section of an implant. Niznick, col. 41-55. Therefore, the Examiner’s reliance on M.P.E.P. 2123 is misplaced. All of the disclosure of Niznick is directed to a surface texture with 25 micron or greater peak-to-valley height within the middle region, and 20 micron or greater peak-to-valley height within the rest of the implant and, thus all of Niznick’s disclosure has been considered, not simply selected specific embodiments.

Consequently, while Haruyuki teaches the skilled artisan to avoid surfaces where the peak-to-valley height of the surface texture is greater than 5 microns because of potential biological problems, such as cancer, Niznick teaches that same skilled artisan to employ a surface where the peak-to-valley height of the surface texture is 25 microns or greater in some regions and at least 20 microns or greater over the entire implant. In fact, Haruyuki teaches that a 10 micron surface may not even function to allow bone cell attachment. Niznick teaches a minimum surface texture that Haruyuki teaches is not even functional. The Federal Circuit has stated “if references taken in combination would produce a ‘seemingly inoperative device,’ we have held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness.” *McGinley*, 262 F.3d at 1354 (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). A skilled artisan would find the teachings of Haruyuki and Niznick would produce a “seemingly inoperative device,” and thus the

combination of these references may not form a *prima facie* case of obviousness. The Answer states, “the Examiner Asserts that since both references are concerned with rough surfaces for the purpose of ongrowth and ingrowth that the different dimensions alone do not make them incompatible.” Answer, p. 6. That statement is in error. Haruyuki believes that a very “rough” surface like Niznick’s surface is inoperative. Niznick believes that a “smooth” surface like Haruyuki’s surface is inoperative. Thus, Haruyuki teaches away from Niznick. *Monarch Knitting*, 139 F.3d at 885. The skilled artisan would never combine these two references.

Further, the differences between the surface texture taught by Haruyuki and the surface texture taught by Niznick also relate to the formation of the surface texture itself. Niznick teaches that the surface texture with the peak-to-valley heights of 25 microns or greater should be created from an HA (hydroxylapatite) coating, TPS (titanium plasma spray) coating, or grit blasting, all of which introduce foreign matter to the underlying implant surface. Niznick, Col. 7, lines 17-18 and 47-48.

However, Haruyuki teaches the skilled artisan of the problems associated with these type of material-adding process, such as introducing “biotissue contamination” to the patient, and/or operational complexity and high-cost. Haruyuki, p. 3, col. 1. As such, this is yet another direct contradiction between Haruyuki and Niznick teachings on surface texture. The Appellants’ respectfully note that the Answer did not even address the incompatibility of the manner of producing the surface of Haruyuki and the surfaces of Niznick in the Answer. Thus, a skilled artisan would be “discouraged from following the path” set out in Niznick by the disclosure of Haruyuki. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Additionally, Niznick teaches a smoother top portion and bottom portion compared to the middle portion of an implant. Appeal Brief, p. 12. The Answer in no way addresses why the entire teaching of Niznick of a smoother lower section was not considered by the Examiner. However, the law of obviousness requires that a reference be considered as a whole, including those portions that teach away from the Applicant’s claimed invention. *See W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.3d 1540, 1550-51, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983) (“[T]he totality of a reference’s teaching must be considered.”). Haruyuki teaches an surface that may be used on an implant but never discloses where to locate a roughened surface on the dental implant. As a smoother lower section teaches away from the Applicants’ claimed invention, Niznick

teaches away from the claimed invention, as an artisan “would be led in a direction divergent from the path taken by the applicant.” *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001).

It is axiomatic that the entire teachings of the references must be considered when determining obviousness. When doing so here, the skilled artisan would never combine the teachings of Niznick with those of Haruyuki to produce Appellants’ invention of claims 51 and 60-75. As stated by the Federal Circuit “[t]here is no suggestion to combine, however, if a reference teaches away from its combination with another source.” *Tec Air, Inc. v. Denso Mfg. Michigan*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). Haruyuki and Niznick clearly teach away from each other. It is axiomatic that prior art references simply cannot be serve to create a *prima facie* case of obviousness where the references teach away from their combination, thus Haruyuki and Niznick may not form a *prima facie* case of obviousness.. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001).

5. Niznick Teaches Away From The Claimed Inventions

The Applicants provided substantial arguments as to why Niznick teaches away from the claimed invention. Appeal Brief, p. 12. The Answer provides no response to this point of contention.

6. Niznick and Haruyuki Do Not Teach All of the Elements of Claim 63.

Claim 63 includes limitations regarding the self-tapping feature of the dental implant and, specifically, that the acid-etched surface with the substantially uniform array of irregularities is located within the self-tapping feature. Appeal Brief, p. 13. Other than a simple statement that Niznick teaches that it was “known in the art to have ... a self-tapping feature,” (Answer, p. 4), the Answer fails to address the elements concerning the acid-etched surface having a substantially uniform array of irregularities extending along the threaded portion and into the self-tapping feature.

Haruyuki simply mentions his surface could be used on dental implants. But, Haruyuki fails to teach (i) where to locate any roughened surface on the dental implant, (ii) what type of dental implant he is referring to, and (iii) why a roughened surface should be at only certain locations on the dental implant, as opposed to a smooth surface on other locations.

Further, Niznick does **not** teach an acid-etched surface that extends along the threaded portion of the dental implant, into the self-tapping region, and to the lowermost end of the implant. Again, the middle threaded portion of Niznick's implant that is roughened (to 25 microns or greater) does **not** extend to the lowermost end of the implant or into the self-tapping region. As such, Niznick fails to teach the features of claims 63-66, and actually teaches away from it. Simply put, Niznick fails to overcome the deficiencies of Haruyuki.

7. Niznick and Haruyuki Do Not Teach All of the Elements of Claim 68.

Claim 68 requires cylindrical and tapered sections and a self-tapping region within the tapered section. An acid-etched surface **extends from the lowermost end, through the self-tapping region, and into the cylindrical section.** The acid-etched surface has a substantially uniform array of irregularities having peak-to-valley heights no greater than about 10 microns. Other than a simple statement that Niznick teaches that it was "known in the art have ... a self-tapping feature," (Answer, p. 4), the Answer fails to address the elements concerning the acid-etched surface having a substantially uniform array of irregularities extending along the cylindrical and tapered sections portion and into the self-tapping feature.

Haruyuki simply mentions his surface could be used on dental implants. But, Haruyuki fails to teach (i) where to locate any roughened surface on the dental implant, (ii) what type of dental implant he is referring to, and (iii) why a roughened surface should be at only certain locations on the dental implant, as opposed to a smooth surface on other locations

Niznick, on the other hand, does **not** teach an acid-etched surface extending from the lowermost end, through the self-tapping region, and into the cylindrical section. The middle threaded portion of Niznick's implant includes an extremely rough surface having peak-to-valley heights of greater than 25 microns. Of course, Niznick's roughen surface does **not** extend from the lowermost end of the implant, into the self-tapping region, and into the cylindrical section. As such, Niznick not only does not suggest the configuration of claims 68-71 and 73-75, but actually teaches away from it. Niznick fails to overcome the deficiencies of Haruyuki..

8. Niznick and Haruyuki Do Not Teach All of the Elements of Dependent Claims 61, 67, and 72.

Claims 61, 67, and 72 are separately patentable for the reason that not all of the elements of claims 61, 67, and 72 are taught in Haruyuki or Niznick. The Answer fails to address the

“sulfuric acid” and “hydrochloric acid” elements that produced the acid-etched surface. To the extent that that Examiner’s position is that these are product by process claims, the Applicant’s respectfully suggest that the Examiner cannot completely ignore the plain language of the claims in presenting a case of obviousness. The Applicants note that they have submitted evidence showing that different acids do not produce the same results. See Gubbi Declaration; Appeal Brief, Ex. I, ¶ I-K. Further, Haruyuki does not desire a solution that would further roughen the surface, like the mixture of sulfuric and hydrochloric acids. Instead, Haruyuki wants a solution to smoothen the roughened surface, which would not happen with sulfuric and hydrochloric acids.

9. The Declaration of Dr. Porter

The Applicants spent considerable time developing a good-faith effort to demonstrate secondary evidence of non-obviousness. The Examiner summarily dismissed of Dr. Porter’s Declaration. The Applicants preserved this position for appeal and, in the Appeal Brief, set forth several contentions as to why the Examiner’s position was in error.

Yet, the Answer fails to address the Declaration of Dr. Porter.

CONCLUSION

For at least the foregoing reasons and the reasons stated in the Applicants' Appeal Brief, the rejection of claims 51 and 60-75 should be reversed.

Enclosed herewith is a Request for Oral Hearing along with the fee of \$1000 required by 37 C.F.R. 41.20(b)(3).

No fee is believed due in connection with the filing of this Reply Brief. However, if Appellants' are in error, the Commissioner is authorized to charge any additional fees inadvertently omitted that may be required (except the issue fee) now or during the pendency of this application to JENKENS & GILCHRIST, P.C. Deposit Account No. 10-0447(47168-00035USC1).

Respectfully submitted,



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